Ventricular Tachycardia Database Development and Detection

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Dr. Kashou: Welcome to Mayo Clinic's ECG segment, Making Waves. We're so glad you could join us. Today, we have an exciting episode planned for you as we look at the development of an annotated ventricular tachycardia database designed to improve hospital-based ECG monitoring. We have an expert discussant joining us who will help us better understand this topic. ECG monitoring is an essential aspect of patient care. For instance, early detection of ventricular tachycardia in hospitalized patients can improve the morbidity and survival of patients. Unfortunately, the accuracy and reliability of hospital based ECG monitoring software is encumbered with false alarms. In this episode, we will look at the creation of a ventricular tachycardia database to help tackle this problem. We're fortunate to have Dr. Michele Pelter here with us today to discuss this further. Dr. Pelter is an associate professor in the School of Nursing at the University of California San Francisco. Dr. Pelter completed an undergraduate nursing degree in 1988 from the University of Nevada Reno. She worked as a clinical nurse in the cardiac telemetry unit and then the cardiac intensive care unit during which time she developed a special interest in electrocardiology. Dr. Pelter went on to earn both a master's and PhD in nursing from UCSF, where she focused her studies in ECG monitoring of adult patients. The overarching goal of Dr. Pelter's research is to increase the accuracy and maximize the utility of hospital-based ECG monitoring. Specifically, Dr. Pelter's work has focused on improving the detection of transient myocardial ischemia and most recently understanding false ECG alarms that might contribute to alarm fatigue in nurses. Dr. Pelter's work has been published and presented broadly, including over 90 database papers, over 120 non-database papers, eight book chapters, and more than 80 scientific presentations at both national and international meetings. Since 2001, Dr. Pelter has co-authored the ECG puzzler, a regular feature in the American Journal of Critical Care. While Dr. Pelter is a clinical researcher, for the past several years, she has been collaborating with biomedical engineers to develop and test ECG algorithms using both signal processing and machine learning approaches. This has been possible in large part due to collaborations with the Center for Physiologic Research located in the UCSF School of Nursing. In 2019, Dr. Pelter was appointed a translational scientist in the Center for Physiologic Research, which supported the algorithm development and annotation protocol that we will discuss today. Dr. Pelter, what an honor to have you joining us today. I'm so excited to talk to you. Thank you for joining us.

Dr. Pelter: Thank you so much for the invitation.

Dr. Kashou: You know, so what I thought is, you know today we're gonna be learning a lot about what you have in the development of this annotated ventricular tachycardia or VT database you've created to improve this identification of ventricular arrhythmias in the hospital setting. But perhaps before we even get into all the details, you can share why is this such a problem today?

Dr. Pelter: Well, since 2015, I've been studying the problem of false ECG alarms that are associated with alarm fatigue, as you mentioned in your introduction there, and alarm fatigue occurs when clinicians are exposed to high numbers of alarms from medical devices that are used in the hospital. And because I'm a nurse scientist, most of my work has been looking at this in nurses. However, physicians and other providers who work closely with these devices experience this problem as well. And just to give you an idea of the number of alarms that are coming from those in this case I'm talking about bedside monitors in the intensive care unit. In the UCSF alarm study, in a one month period we found that there were over 2.5 million alarms. And again, these would be for both BCG alarms as well as vital signs and things of that nature. Anything that comes out of that bedside monitor. And when you look at the audible alarm rate from that database, again, not all of the alarms are audible. Some flash a text message on the bedside monitor. But if you look at just the audible alarms there was 187 alarms per bed per day and 90% of the ECG arrhythmia alarms were false. And this repeated exposure to neverending alarms. What we have found is that often nurses start to assimilate that noise into their workflow and they can unintentionally miss a true alarm because of that. We also know that there's a delay in response. So the more exposure over time that you have to alarms you start to delay responding to those. And then lastly, there's unsafe alarm adjustments that happen. So nurses might turn the volume down. And in extreme cases, they turn the alarm off altogether. And of course this creates a problem because true events can be missed. And we know from data, which is, unfortunately, 10 years old that there's been 650 deaths related to alarm fatigue. And again, those are rather old statistics. And I know that this problem hasn't gone away. So I suspect the morbidity mortality is more than those data show us. And in fact, the Joint Commission identified alarm fatigue as a national patient safety goal. And hospitals are required to reduce the harm associated with alarms. So it's an important problem that hospitals need to solve. So, following the UCSF alarm study where we reported those 2.5 million alarms, our group has really been trying to understand, specifically, the ECG alarms and why they happen. And a widely held belief is that it's really a nursing issue, that it's electrode contact, not changing skin electrodes and things of that nature. And because of that, a lot of clinical scientists have looked at trying to solve this problem through electrode changes, disposable lead wires, you know, things of that nature to solve this problem. But what we've found is that only 9% of arrhythmia alarms are due to poor signal quality. And that is, you know, unanalyzable ECG due to excessive noise based on wander, et cetera. But what we've actually learned through looking carefully at the alarms is that the primary source of these alarms is really algorithms themselves. And for example, we found that ECG abnormalities such as bundle branch block, both left and right, ventricular pace rhythms and low amplitude QRS complexes are a major source of a lot of these alarms. So you know, all this to say that, you know, skin electrode changes and all of that do have a place that they are not going to make a very large impact on false alarms in a meaningful way.

Dr. Kashou: It is quite striking. And I know you, you mentioned false, you know, ECG alarms we're talking about, but I know you probably can empathize or other medical professionals is that there's alarm fatigue probably across a lot of areas of medicine whether it's the in-basket from, you know, patient messaging. But this is such an important one because in the critical care setting, we're looking after so many aspects in these alarms, as you mentioned, if you, know now nursing's becoming fatigued to them and there's actually a real event, well, we don't want to miss

those. And now with the evolution of different hardware and software devices, important that we kind of step back and look at this. And so I guess the next question is why is your group focusing specifically on ventricular tachycardia?

Dr. Pelter: So our group identified ventricular tachycardia as one of the most problematic lethal arrhythmias and we care about lethal arrhythmias because they can lead to in-hospital cardiac arrest. So immediate identification of these types of alarms is really important. And this type of alarm, these lethal arrhythmia alarms, are configured as latching or crisis-level alarms. And that particular alarm makes a constant high pitched sound to get the nurse's attention, or physician's, provider's, and it cannot be silenced until the nurse physically pushes a button to stop it, either at the bedside or a central monitoring station if you happen to have monitor watchers. So then the nurse has to analyze that rhythm strip and determine if it's true or false. So, of the lethal arrhythmia alarms, and these would include asystole, ventricular fibrillation, and ventricular tachycardia. VT is the most problematic, with up to 90% of those alarms false. When we look at asystole, 67%, so still a high proportion, and 32% of ventricular fibrillation. So of those three types of lethal arrhythmia alarms, VT is the most common. So if you look at how often they're sounding, 80% will be for ventricular tachycardia, 17 asystole, and 3% for ventricular fibrillation. So given that our group thought that addressing ventricular tachycardia would make a huge impact, we think, in false alarm reduction and of course hopefully decrease the harm associated with missed VT events.

Dr. Kashou: That makes sense. And so what I've learned so far is that, you know, we have these monitors in throughout the hospital and now in the home setting. But the ones in the critical care where you focus your attention is, you know, there's a lot of alarms. And of those alarms, a lot of them are actually false. Right? And then of the false alarms, you know, it's not really even the attachment of the electrodes that's causing it, but it's more of potentially the software that is kind of the primary source of where you're seeing this in VT, representing, you know, a lethal rhythm as asystole and ventricular fibrillation, is the most common one you guys have have come across. I guess because now we're saying the source is these algorithms, where do you see the deficiencies in these algorithms?

Dr. Pelter: So what we have been doing for the past several years is really trying to understand, what are the sources of the false alarms? And with that knowledge, can we come up with algorithm solutions on our own or help guide industry in knowing what those are? So, of course, one source of false ventricular tachycardia is artifact. And because we don't want to miss any of those types of events, algorithms are designed with a high degree of sensitivity. And unfortunately this means there's a tendency for current VT algorithms to react to noise and artifact in the ECG waveforms. And because, you know, while artifact is common, you know, again, we're talking about continuous monitoring. So you've got patient movement, interference with other devices, and just routine patient care. What we've found is that not all of the ECG leads are affected with that type of noise. So let's take for example, artifact that mimics VT. And what we have found is it's often associated with a particular skin electrode on the body's surface, and it can cause these pseudo-VT looking rhythms that can cause an alarm. So let's take an example of a patient maybe scratching their head. What would be impacted is that right arm electrode. And so any lead that uses the right arm in its signature to create that lead, you can see the pseudo VT in all of those leads. So in our example of the right arm, everything that would be

impacted in terms of the leads is leads one, lead two, the augmented unipolar leads, AVR, AVL, and AVF, as well as the V lead. We typically monitor in B1 because the Wilson Central terminal, of course, uses the right arm electrode in its signature. However, if you look closely at the entire rhythm strip, what you'll see is that lead three will look very clean because it uses the left arm in its signature. And so if you were to look at the entire rhythm script what you would see is a clean QRS, a P wave with sinus even if it's atrial fibrillation, you would definitely see discernible QRS. And one of the limitations of current algorithms is they require a clean signal in more than two ECG leads. So even though we have one lead that looks really clean, you will get a ventricular tachycardia alarm. And so that is one of the things that we've found. So our algorithm approach has been to look at if you have a clean signal in any one lead, we will not alarm for that. And you can enhance that particular situation by using either SPO2 or the arterial blood pressure if a patient has that. And by combining those two, you can have confidence that not only do you have a stable lead that is clean, but you have an SPO2 or arterial blood pressure that looks clean as well. And current algorithms do not coalesce those two waveforms. So that can be an issue. Another algorithm issue we identified that contributes to false VT is underlying bundle branch block, again, either left or right and ventricular pace rhythms. And in both of these conditions, because the QRS is wide and if the heart rate exceeds a hundred beats per minute, that can look like ventricular tachycardia and the algorithm will recognize it as that and generate an alarm. And of course, in hospitalized patients, it is not uncommon for us to see bundle branch blocks, paced rhythms and so forth. And so in that subset of patients, they can generate a lot of false alarms for ventricular tachycardia. So the algorithms currently don't have the ability to sort of learn the patient's baseline rhythm or account for pace rhythms. The nurse has to typically turn on the pacer mode feature to change the filter settings to detect that. So, of course, the question that comes up is, you know, why do the monitors have these deficiencies? I don't see this as a lack of desire by the monitoring manufacturers. They're very, you know, the engineers that I've worked with from several monitoring companies really have a desire to change this product. What we think is that the lack of robust and contemporary databases that monitoring manufacturers use to test and develop new algorithms are very outdated. The current databases available from the FDA are over 40 years old. They are two channel filter recorders, small numbers of patients, small numbers of arrhythmias, and so they don't really represent hospitalized patients. And therefore, you know, having improvements to this using those databases is going to be pretty minimal. And that's why we've really seen advances in arrhythmia analysis software has been kinda stalled for decades. So based on all of this, our group saw a real opportunity to not only develop and test our new algorithm, but also create a contemporary database that could be used by device manufacturers, the FDA. And this could lead to better benchmarking data that could tell us the accuracy, sensitivity, specificity of arrhythmia software that would really help, I think, move the field. And so to seize on this opportunity, our group has recently completed a VT annotation protocol. And we have a sophisticated data capture system in our intensive care units where, in the background, we capture all of the information from those bedside monitors. And so we've been collecting these data since 2013. And so what we had was a sample of 5,320 consecutive ICU patients and we're talking over 570 hours of monitoring. So a huge amount of data. And what we did is we processed our new BT algorithm on this database, and then we had five nurse scientists experts who are advanced practice nurses, annotate these data as true and false. And so what we were able to do was not only test our BT algorithm, but create this database that we hope to share with the Food and Drug Administration that could then be used by monitoring companies and, you know, using this sort of regulatory pathway, you

know, we're hoping that that would serve monitoring manufacturers well in, you know, developing their algorithms to improve them.

Dr. Kashou: It's quite remarkable, you know, to see where you've went through, you know, first identifying the problem, then seeing the problem and focusing on ventricular tachycardia. Now creating a database that could be used by others to test, but really for that vision of improving, right? These old data sets that you said are, you know, 40 plus years, but giving us a contemporary way to test and improve and hopefully detect this lethal arrhythmia with better, you know, with maybe better specificity, right? Right now our sensitivities are so high, if we could lower that, lower, potentially, the burden that nurses and our colleagues are facing, it's just quite remarkable. And you can certainly see how this would improve, you know, that scenario. Is there any other thoughts on that topic that you want to share? Otherwise, I would love to see what else, you know, your group is working on because I'm always amazed to read about, you know, this. This is the first time, I learned about it at our conference, but you guys have a lot of interesting work going on.

Dr. Pelter: Yeah, maybe what I'll first discuss with you is the performance of our algorithm. So of the 5,320 patients, to be exact, 15% of that group had one or more VT events. And so 15% of the sample. If you look at the current bedside monitor, in that same sample, 30% of that group had a VT event. So we've sort of, and that sounds high to me, 30%, I think 15% is probably more in line with the truth, perhaps. So, of those alarms, what we've found that it generated 22,300 alarms. And when we annotated that, and I should mention our annotation effort were really pleased with how we approached it. Each VT alarm that was generated with our algorithm required three person agreement. And so if three did not agree with the diagnosis, it went to a fourth person, and if there was still disagreement, it went to a cardiology panel. So, we really feel like we're pretty close to the truth, if you will, in terms of the annotation protocol. And what we found was that there were 65% of the VT events were true, and 35% were false. And you know, we still have work to do, that's still a lot of false alarms. But if you look at the current bedside monitor in a separate analysis, we found that only 13% of the VT events were true, using the current bedside monitor. So we feel like a 65% true rate is pretty good and we're pretty excited about that. And one of the things that we learned was that there is a subgroup of patients, it's only 2% of the sample, who've had one or more VT events had what we call unresolved VT alarms. And these were patients often who, again, had bundle branch block, ventricular pace rhythms, and again, heart rates that exceeded that hundred beats per minute. And so, all this to say, in clinical practice, it is mighty hard to interpret these ECGs. It takes a lot of skill to look at them and to really look at the whole picture of what's going on with that patient to get at the truth. So, you know, again, the database has not only true and false VT that we can learn from, but these unresolved issues will be really important too to help us kind of hone in on true VT.

Dr. Kashou: Amazing. I am in, I presume that, you know, using those results and seeing your algorithm's performance and probably you're gonna want to even do more to improve on that. The goal is to minimize those alarms, minimize the fatigue and burden that, you know, all providers are now tasked with more assignments. And so I applaud, it's amazing just the work you've done and just knowing, working in the hospital and seeing this as probably one of the most difficult skills to have is, like you said, interpreting, getting to the truth, right? And it relies

on a lot of data. So thank you to you and your group and any other final thoughts or other work that you'd like to share with us?

Dr. Pelter: You know, one other that might be of interest is other alarms. And so one of the, the studies we just completed was looking at premature ventricular contractions. So PVCs, and when you look at all of the various alarms, PVCs represent the highest proportion of alarms. So, in that UCSF alarm study, during just that one month period, there were over 850,000 PVC alarms. So a lot of alarms. And when you look at the various types, by the way, most monitoring manufacturers have several PVC types that they monitor for. Isolated, of course, bigeminy, trigeminy, R-on-T, there's various types. By far isolated are the most common. And when we looked at whether these PVC alarms were associated with ventricular tachycardia, when you adjust for things like heart disease, ejection fraction, PVCs, on a standard 12 lead, when you're admitted, we did not find an association between PVCs and ventricular tachycardia. So, you know, it may be that we're over-monitoring for something like premature ventricular contractions that we don't typically treat all of those in a patient. So here is where we're kind of thinking about guidance on what we should be monitoring for. And I think turning on PVC alarms may not be a great clinical move. It really kind of contributes, again, to a lot of alarms. Now, one could argue, typically PVCs are configured as an inaudible text message that flashes on the bedside monitor, but we know that nurses are still distracted by that because they look up at the monitor, wonder what it is, oh, it's a PVC, and then have to think through whether they need to do anything with that. So, you know, our guidance to clinicians, to really think thoughtfully about whether you wanna turn that particular type of alarm on. So that's just some of the work is, you know, also kind of thinking about, you know, what do we really need to monitor for? As an electrophysiologist, you're probably very interested in PVCs, but you know, do we need to carefully monitor for those in hospitalized patients in a continuous way?

Dr. Kashou: Yeah, that's so fascinating. And I mean, you're already tackling VT as the, you know, the most common, the lethal one, but PVCs, you know, well, we don't think of them so much. They are, you know, the most common and perhaps maybe you guys could consider, and the, you know, even a burden, right? You're looking at what is the PVC burden and if it's already below that, maybe we'll just shut it off for the patient, you know? So, I don't know. I'm sure you guys have a lot of better ideas and I'm just kind of thinking off the cuff, but such great work. Hospitalized-based ECG monitoring is a routine part of patient care. Early and accurate detection of ventricular arrhythmias can be lifesaving. However, as we learned today, there are limitations in existing ECG interpretation software at the bedside. Improvements in such technology might not only reduce false alarms, but also improve patient outcomes. Dr. Pelter, I've learned a lot from our discussion and from in the past. It's so exciting to see all the work you and your group is doing in hospital-based ECG monitoring. On behalf of our team, thank you so much for taking time out of your day to join us.

Dr. Pelter: Thank you so much for inviting me.

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